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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/612,418 | 07/07/2000 | Raymond P. Johnston | 54971USA3A.006 | 8574 |

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| EXAMINER |
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MARSCHER, ARDIN H

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| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 08/18/2003

241

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary

Application No.

09/612,418

Applicant(s)

JOHNSTON ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77 and 81-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s) 20, 22, 23
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19. 6) ☐ Other:

DETAILED ACTION

The amendment, filed 5/12/03, has been entered. Due to the newly applied rejections summarized below, the finality of the office action, mailed 2/18/03, is hereby withdrawn.

Applicants' arguments, filed 5/12/03, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

ABSTRACT

The abstract of the disclosure is objected to because it exceeds 150 words in length. A new abstract of 150 words or less must be submitted on its own separate sheet of paper. Correction is required. See MPEP § 608.01(b).

VAGUENESS AND INDEFINITENESS

Claims 1-9, 13, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 77, and 81-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is acknowledged that the specification has been amended at page 12 to include a definition of a "film" and the production of structured polymeric film layers via microreplication. This section defines the film of the instant invention as being "generally flexible". This causes the instant claims to be vague and indefinite as to what

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the metes and bounds of this phrase are regarding the “film” limitations in the instant claims. For example, does “generally” intend to be interpreted as a limitation on flexibility for all films of the instant invention or should it be interpreted as being equivalent to the word “about”? These are both possible reasonable interpretations of “generally” but one interpretation requires flexibility for all films of the instant invention whereas another interpretation is inclusive of no flexibility. Additionally, the word “flexible” may be reasonably interpreted in various ways. In one interpretation, it may be considered that all materials have some flexibility, albeit some very little, in which case, it is confusing as to what is meant by describing a film as being “flexible”. In another interpretation some amount of flexibility is meant above some threshold such that a film of the instant invention is normally considered a flexible material rather than a rigid material. No threshold, however, for flexibility has been set forth that has been found as filed, in the instant specification. In yet another interpretation flexibility of manufacture may be meant rather than a characterization of a flexing ability of a film as claimed. Clarification of the metes and bounds of the above phrase, which is apparently meant to be a limitation regarding the film as instantly claimed, is requested. This unclarity is also present in claims which are dependent directly or indirectly from instant claim 1 due to their dependence.

Claim 1, line 4, sets forth the phrase “uninterrupted fluid flow of a fluid sample”. This phrase causes the claim to be vague and indefinite as to what is meant thereby. One possible interpretation is that the sample flows as a fluid without interruption of its being a sample per se. This interpretation, however, conflicts with the limitations in

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lines 4-6, wherein a plurality of microchannels draw the fluid sample into a plurality of microchannels through openings (plural). This is illustrated, for example, in Figure 6c wherein each of several microchannels is interrupted by two separating walls to result in a plurality of microchannels each with its own opening defined by walls which divide the sample. Thus, the sample is no longer a sample per se but a plurality of sub-samples divided by said walls. Since instant claim 1 requires a plurality of microchannels into which a sample is drawn, the sample fluid flow must be interrupted in order to be subdivided into said plurality of microchannels. Another interpretation is that no valves control sample flow. This interpretation, however, is confusing in that valves normally are either open or closed. The open position is understood to permit uninterrupted fluid flow in a microchannel, even though it is possible to have the flow interrupted at another time by closing of the valve. Clarification of the metes and bounds of the above phrase is requested. This unclarity is also present in claims which are dependent directly or indirectly from instant claim 1 due to their dependence.

Claim 1, line 7, sets forth the limitation "by spontaneous fluid transport". The limitation "spontaneous" is not instantly specifically defined. Therefore, the normal and customary definition is a possible definition. The word "spontaneous" is defined in the WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY on page 1123 as definition 1 as "occurring without apparent external cause". This definition seems closest to its usage in the instant claims. Within this definition is the word "external". No instant definition of what is external has instantly been set forth for the practice of the limitation "spontaneous". Thus a number of possible interpretations can be utilized.

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One is that the external cause is external to the sample. This, however, is confusing because wicking and capillary action are instantly described for fluid flow which both occur via interaction external to the sample with a microchannel wall. The forces which draw sample into a microchannel via wicking or capillary action are dependent on wetting of a surface, such as a microchannel surface, with sample which then results in a force on the sample as caused by the microchannel wall. The wall may be interpreted reasonably as being external to the sample. Another possible interpretation is that the external cause is external to the claimed detection article, cited in line 1 of claim 1. Thus, any fluid transport caused by structures inside or internal to the "detection article" may be considered spontaneous as viewed by someone who is external to the claimed "detection article". Therefore, electrophoretic transport of fluids in a device with microchannels utilizes electrodes within the device or article and may be interpreted as spontaneous within the instant claims. The above interpretations are different in metes and bounds and result in unclarity of the instant claims. Clarification of the metes and bounds of the above phrase, which is apparently meant to be a limitation regarding the film as instantly claimed, is requested. This unclarity is also present in claims which are dependent directly or indirectly from instant claim 1 due to their dependence.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60, 61, 72-75, 81, and 83-85 are rejected under 35 U.S.C. 102(e)(2) as being clearly anticipated by Alajoki et al. (P/N 6,416,642).

Microfluidic devices for fluid flow therein are summarized in the abstract. The dimensions of fluid conduits or microchannels as instantly claimed are set forth in column 4, lines 11-30. These devices may be made of plastics as cited therein which are flexible both in manufacture as well as in flexing character. These devices include junctions connecting one or more channels as in the instant claims in column 5, lines 5-12, as well as depicting in Figures 1 – 3A. Detection is also practiced in the devices of the reference as set forth in column 5, lines 41-48. The devices utilize continuous flow as set forth in column 5, lines 49-56, which anticipates the uninterrupted flow of the instant claims. The detection practice available in the device of the reference is detailed more specifically regarding reagents utilized for that purpose in column 12, line 38, through column 21, line 32. Wicking (hydrophilic as in claims 6 and 7) and other fluid transport practice for the device of the reference is described in column 21, line 35, through column 23, line 22, wherein continuous, or uninterrupted fluid flow is cited in column 23, lines 18-22. Polymeric materials that make up the device are described in column 22, lines 37-59, as also instantly claimed. Both sample introduction wells as well as detection chambers etc. are described in column 23, lines 1-35, which disclose

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the acquisition and detection zones as well as intermediate zones or connecting channels (instant claim 5) as instantly claimed. These disclosures anticipate the above listed instant claims.

Claims 1-7, 39-41, 43-46, 49, 50, 53, 54, 60, 61, 72-75, 81, and 83-85 are rejected under 35 U.S.C. 102(b) and (e)(2) as being clearly anticipated by Christian (P/N 4,673,657).

Christian discloses an assay card with channels and chambers interconnected with flexible elements in the abstract for a variety of assays. A plurality of different assays, up to 250, may be performed therein as disclosed in column 3, lines 6-51. A variety of steps may be programmed in the card as described in column 4, lines 34-54, as required in instant claim 4. Layers with microassay components are made up of small thicknesses and sizes as in column 7, lines 3-36, including polymeric nitrocellulose materials, as also describing the microchannel sizes as instantly claimed. Nitrocellulose is well known to be wettable and therefore hydrophilic as required in instant claims 6 and 7. The assay is performed in a microassay card format as described in column 14, line 23, through column 17, line 45, as well as in Figures 12 and 13 as described in column 12, line 12, through column 13, line 2, describing microchannels therein with acquisition, detection, and intermediate zones. These disclosures anticipate the above listed instant claims.

INFORMALITIES

The disclosure is objected to because of the following informalities:

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In the specification on page 57, line 26, the word "Triton" appears to be misspelled.

The use of the trademark TRITON has been noted in this application, assuming that the spelling correction is performed as required above. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 14, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER